

We are committed to—

Strengthening Immunization Science and Communicating Results

The National Immunization Program (NIP) undertakes and promotes a wide range of scientific activities, including epidemiologic and surveillance studies, disease outbreak investigations, evaluations of health care delivery methods and systems, and social and behavioral science research. Importantly, NIP works to translate research finding into actions and recommendations and to communicate these activities to the appropriate audiences.



Vaccine Protection Expanded

Today, the childhood immunization schedule recommends that all children in the United States be protected against 11 vaccine-preventable diseases. This ability to protect children and adults from vaccine-preventable diseases stems directly from NIP's commitment to disease prevention. Strengthening immunization science and communicating the results are key components in our effort to expand vaccine protection.



The National Immunization Program conducts research with a number of partners, including research universities and health departments, to develop and evaluate immunization recommendations and programs. Epidemiologists, physicians, and scientists from NIP are involved in clinical trials, disease surveillance studies, disease outbreak investigations, and studies designed to improve the safety, effectiveness, and delivery of vaccines.

Importantly, NIP disseminates new immunization recommendations and relevant findings from research or field experience as quickly as possible so public health officials, health care providers, and others can act upon the information. Up-to-date information and resources are posted on NIP's website and links are provided to a number of other related sites.

Major Events of the Past Year— in Vaccine Protection

PNEUMOCOCCAL CONJUGATE VACCINE IMPACT DOCUMENTED

The pneumococcal conjugate vaccine (PCV) was added to the CDC recommendations for routine childhood immunization in April 2000. Pneumococcal infections are the leading cause of serious illnesses among young children, especially those under 2 years of age, and are the most frequent cause of meningitis, bacterial pneumonia, and bloodstream infections.

The effectiveness of this vaccine was documented in 2001 in a study involving a large managed care organization. A substantial reduction in invasive pneumococcal disease incidence among children younger than 5 years old was observed following introduction and routine use of PCV.

It is projected that, once fully implemented, PCV will prevent over one million episodes of childhood illness and approximately 120 childhood deaths each year. In

2001, a total of 8.4 million doses of PCV were purchased through the CDC's federal contract. This is 5 million more doses than were purchased in 2000.

INACTIVATED POLIOVIRUS VACCINE RECOMMENDATION

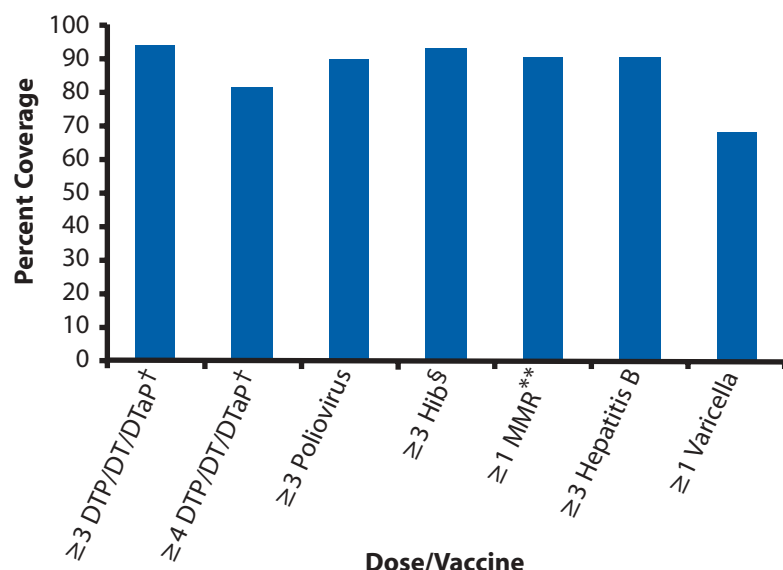
Only inactivated poliovirus vaccine (IPV) is used for routine childhood immunization in the United States. Because the global polio eradication initiative has progressed rapidly, and the likelihood of poliovirus importation into the United States has decreased substantially, the Advisory Committee on Immunization Practices (ACIP) concluded that the risks of oral poliovirus vaccine (OPV) currently outweigh the benefits in the United States. The ACIP maintains its support, however, for the use of OPV as the only vaccine recommended to eradicate polio from the remaining countries where polio is endemic.

VARICELLA (CHICKENPOX) VACCINE

In 1995, the U.S. became the first country to recommend the varicella vaccine for routine childhood immunization. Before the introduction of this vaccine, 3 to 4 million cases of varicella occurred each year, resulting in approximately 11,000 hospitalizations and 100 deaths each year.

By 2001, the number of varicella cases and hospitalizations dropped 70 to 80 percent from the pre-vaccine era. The number of chickenpox cases has declined in all age groups, as has the number of outbreaks and the number of days missed from school. Many areas of the country report a progressive reduction in varicella cases since 1999, and several states with consistent varicella case reporting recognized a 75 to 80 percent decline in reported cases in 2001. While the safe and effective varicella vaccine has greatly reduced the impact of this disease, the varicella virus is still prevalent in the U.S.

Vaccination Coverage Levels Among Children Aged 19-35 Months, by Selected Vaccines, National Immunization Survey, United States, 2000*



* Born during February 1997-May 1999

† Diphtheria and tetanus toxoids and pertussis vaccine, diphtheria and tetanus toxoids, and diphtheria and tetanus toxoids and acellular pertussis vaccine

§ *Haemophilus influenzae* type b

**Measles-mumps-rubella

Significant Achievements— In Vaccine Protection

CHILDHOOD VACCINE-PREVENTABLE DISEASES REDUCED

Polio

Polio caused by the wild polio virus no longer occurs in the U.S. The last case of wild-virus polio, indigenously acquired in the U.S., occurred in 1979, and the last indigenous case in the Western Hemisphere occurred in 1991. Plans are underway to certify global eradication of the disease by 2005.

Measles

Once a routine childhood illness, measles is no longer prevalent in the United States. Only 108 cases (provisional data) were reported in the U.S. in 2001. Forty-seven of those cases are believed to have been brought into the U.S. from other countries.

Rubella

Rubella cases have declined from 57,600 in 1969 when the vaccine was first available, to a total of 19 cases in 2001 (provisional data), and congenital rubella syndrome (CRS) cases have dropped by 99 percent over the same period. In recent years, rubella cases have mainly occurred among foreign-born adults from countries that have either not established, or have just established, national rubella vaccination programs. Only two cases of CRS (provisional data) were reported in 2001 to the CDC National Congenital Rubella Syndrome Registry.

Haemophilus influenzae type b

Haemophilus influenzae type b (Hib) is no longer the leading cause of meningitis among children younger than 5 years old in the United States. This disease was once responsible for 20,000 serious infections among young children each year. However, since 1993 the widespread use of the Hib vaccine has reduced the incidence of Hib invasive disease in children younger than 5 years of age by more than 99 percent.

VACCINE IDENTIFICATION STANDARDS

The Vaccine Identification Standards Initiative (VISI) is designed to improve the accuracy and convenience of transferring information from vaccines into medical records and immunization registries using bar coded peel-off stickers on vaccine vials. This project will help in monitoring any adverse events following vaccination and also assist in tracking vaccine lots for safety surveillance. The overall scope and content of the VISI application guidelines have been completed. In 2002 the guidelines will be compiled into a document for public comment and final publication.



APPLIED RESEARCH AND DEVELOPMENT

Needle-Free Injection Technology

Efforts are being pursued to overcome the drawbacks and limitations of vaccination with conventional needle and syringe. Through Small Business Innovation Research contracts, a new generation of safe, needle-free, high-speed jet injector immunization devices is being developed. These devices could be used for rapid protection of a population against vaccine-preventable diseases (such as mass campaigns to eradicate measles), control of epidemics of meningococcal disease and pandemics of high-mortality influenza, and to help respond to some forms of bioterrorism.

Additional activities include participation in conferences and international standards development for jet injection as well as development of a comprehensive website and news service on needle-free administration of drugs.

Aerosol Vaccination Device

Aerosol vaccination has been shown to be an effective way to deliver measles vaccine; however, the equipment used is cumbersome and has many technical limitations. An aerosol vaccination device designed for mass measles vaccination has been developed by NIP which overcomes the previous limitations. Device development and testing is in progress through a Small Business Innovation Research contract and CDC has applied for a patent. Laboratory tests show the handheld battery powered prototypes deliver live measles vaccine aerosols without loss of potency. Research-in-progress will test the device in animal studies to confirm the safety and immunogenicity of measles vaccine delivered by the device. Phase I trials in humans are planned to begin by the end of 2002.

Potential for Use of Pneumococcal Conjugate Vaccine in the Elderly

The only pneumococcal vaccine currently licensed for use adults is the pneumococcal polysaccharide vaccine (PPV), which provides somewhat limited protection for the elderly. The National Immunization Program and Emory University are planning to conduct a clinical trial to determine if protection can be increased by using a combination of PPV and the new pneumococcal

conjugate vaccine (PCV). This trial will assess the effectiveness of administering a combination of PPV and PCV given with and without a priming dose of tetanus vaccine. If a combination of vaccines is more effective than using PPV alone, studies will be performed to measure how much better this protects the elderly from pneumonia.

Annual Conference on Vaccine Research—Basic Science, Product Development, and Clinical and Field Studies

The Centers for Disease Control and Prevention is a co-sponsor in this conference, which is dedicated exclusively to the research and development of vaccines and associated technologies for disease control through immunization.

SURVEILLANCE AND EVALUATION

National Immunization Survey

The National Immunization Survey (NIS) is the nation's primary tool for assessing immunization coverage among young children in the U.S. This survey is conducted annually by the CDC to obtain national, state, and selected urban-area estimates of vaccination coverage rates for U.S. children aged 19 to 35 months. Households with age-eligible children are surveyed and data collection is limited to children whose immunization history can be verified.

In addition to providing estimates of immunization coverage, the NIS provides other insights into immunization. For example, data from the NIS have recently been used to show that extra-immunization (that is, receiving at least one dose of some antigen in excess of ACIP recommendations) is much less prevalent than previously reported. In 1997, the only year for which extra-immunization had previously been studied, the prevalence of extra-immunization was 21 percent. For 2000, the prevalence of extra-immunization was 11 percent. This dramatic decline represents a substantial savings of resources and a reduction of unnecessary discomfort and inconvenience to children and their parents.

Estimates of immunization coverage for 19 to 35 month old children who had been surveyed in 2000 were

published. The survey revealed that coverage with three or more doses of hepatitis B vaccine had reached a record high of 90.3 percent. Further, coverage with one or more doses of varicella vaccine increased from 57.5 percent during the previous year to 67.8 percent. Overall, coverage for the vaccines routinely recommended for childhood immunizations were at or near record levels.

New Vaccine Surveillance Network

The New Vaccine Surveillance Network was established in 1999 in Monroe County, New York and Davidson County, Tennessee to study the impact of new and prospective vaccines. Site investigators have established year-round inpatient surveillance of acute respiratory infections in children younger than 5 years of age who have been admitted to all study area hospitals. Other network projects include an evaluation of the feasibility of universal influenza recommendations in young children, assessment of pneumococcal conjugate vaccine administration by providers, and analysis of the impact of pneumococcal conjugate vaccination on disease outcomes.

Provider-Based Assessment Tools

Clinic Assessment Software Application software has been developed to allow immunization providers to identify adult and adolescent patients who have a higher

risk of getting a vaccine-preventable disease or suffering complications from such a disease. This software will also help health care providers conduct coverage assessments and produce reports relating to influenza and pneumococcal vaccine coverage and other vaccines in the adult population. The software was tested in San Diego and Oregon during 2001, and the first version will be distributed at the National Immunization Conference in April of 2002.

Improved Influenza and Pneumococcal Vaccination among Seniors in Nursing Homes

In collaboration with their Quality Improvement Organizations, the Centers for Medicare and Medicaid Services has begun a 3-year program to promote standing orders for Medicare patients in nursing homes. The standing orders system enables non-physician personnel in settings such as clinics, hospitals, and nursing homes, to administer appropriate vaccinations without having to get a prescription from individual physicians. Changes in the level of implementation and coverage for influenza and pneumococcal vaccinations will also be evaluated.

SUCCESS STORY

Expanding Vaccine Protection

Varicella (chickenpox) Protection Expanded

By September of 2001, an important step had been made in the effort to protect children against chickenpox. Nineteen states had made chickenpox vaccination a requirement for school entry, and 26 states included the varicella vaccine among their daycare requirements.

Before the introduction of this vaccine in 1995, 3 to 4 million cases of varicella occurred each year, resulting in approximately 11,000 hospitalizations and 100 deaths annually. By 2000, in communities conducting active varicella surveillance, the number of varicella cases and hospitalizations had dropped 70 to 80 percent from the pre-vaccine era, and in 2001 several states with consistent varicella case reporting recognized a 75 to 80 percent decline. While the safe and effective varicella vaccine has greatly reduced the impact of this disease, varicella still remains endemic in the U.S.



Current and Future Activities— in Vaccine Protection

Many new and innovative developments are on the horizon for preventing disease through immunization. For example, in the next few years, a new vaccine for meningococcal disease in infants, an intranasal influenza vaccine for both children and adults, and a combination measles- mumps-rubella-varicella vaccine may be licensed. Additional research is underway to reduce the number of shots children must receive to be fully immunized. This would involve various combinations of the following vaccines: pneumococcal, meningococcal, diphtheria, acellular pertussis, tetanus, hepatitis A & B, polio and Hib vaccines. Taking these new vaccines from development all the way to routine use requires a multifaceted approach encompassing the following components:

Enhanced surveillance to define disease burden, to monitor vaccine impact, and to help ensure the safety and efficacy of each vaccine.

Enhanced assessment of public and health care provider attitudes and behaviors to identify potential barriers to successful vaccine introduction.

Enhanced collaboration with other federal agencies such as the National Institutes of Health and the Food and Drug Administration.

Collection and analysis of new data on vaccine economics and cost-effectiveness as new, more expensive vaccines and combination vaccines are introduced.

Collaboration with international partners to promote introduction of new vaccines in the developing world.

